

MammographyMatters

Winter 1997

Volume 4, Issue 1

From the Editor...

Are you aware of our active presentation and exhibit program? Our staff members regularly make presentations about Mammography Quality Standards Act (MQSA) activities and host MQSA exhibits at various meetings each year.

Most of these meetings have courses that offer continuing education credits. And the availability of our staff affords an opportunity for you to discuss your problems or questions.

Meetings at which we regularly make presentations and/or staff our exhibit, together with this year's dates and sites, plus contact numbers include:

- April 16-19, Society of Breast Imaging, San Diego, California (703-648-8963)
- April 27-30, Conference of Radiation Control Program Directors, Tacoma, Washington (505-227-4543)
- June 21-26, 69th Annual Meeting of the American Society of Radiologic Technologists, Providence, Rhode Island (506-298-4500)
- July 27-31, American Association of Physicists in Medicine, Milwaukee, Wisconsin (301-209-3385)
- August 17-21, American Healthcare Radiology Administrators, Minneapolis, Minnesota (508-443-7591)
- November 30-December 5, Radiological Society of North America, Chicago, Illinois (630-571-7851)

Medical Physicists Meet the MQSA Challenge

In the Fall 1996 issue of *Mammography Matters*, we described the general role and responsibilities of the medical physicist under the Mammography Quality Standards Act (MQSA). For this article, we asked several medical physicists to share their experiences in implementing MQSA and to describe some of the challenges they've faced.

New Role: Team Player

Before the MQSA program was launched, many medical physicists worked independently, often with little or no interaction with facility



Carolyn Kimme-Smith, Ph.D., Associate Professor of Radiology, UCLA School of Medicine



Robert Pizzutiello, Jr., M.S., FACMP, President, Upstate Medical Physics, and his assistant, Victoria Frederic, evaluating a phantom image.

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staff, says Carolyn Kimme-Smith, Ph.D., Associate Professor of Radiology, UCLA School of Medicine. However, she explains, MQSA's team approach to providing mammography services encourages a more active and proactive role for medical physicists. Says Robert (Bob) Pizzutiello, Jr., M.S., FACMP, President, Upstate Medical Physics, "MQSA challenges the medical physicist to a new role that includes one-on-one interaction."

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From the Director . . .

FDA currently is developing regulations for interventional mammography. Recently, we discussed the subject with the National Mammography Quality Assurance Advisory Committee (NMQAAC) and invited guests from medical subspecialties. We plan to continue developing proposed regulations this year and then publish them in the Federal Register in the near future. A period of public comment on the proposal will follow publication. All significant comments will be addressed before we publish the final regulations.

MQSA History with Interventional Mammography

Development of these regulations began in May 1994, when FDA discussed with NMQAAC the possibility of developing standards for interventional technology and personnel. At that time, most NMQAAC members advised us that such regulations were premature. The American College of Radiology (ACR) and the American College of Surgeons (ACS) also participated in those discussions.

During a June 1994 meeting between FDA and the ACR, the ACR supported the position that FDA should not issue regulations on x-ray guided interventional units and personnel. Following that advice, we decided to defer issuing such regulations. In a September 30, 1994, Federal Register notice, FDA wrote, "In the future when the science has advanced to a point where effective national quality standards may develop, FDA may regulate facilities that employ these invasive interventions.."

Less than a year after the NMQAAC meeting, the Society of Breast Imaging called upon FDA to regulate stereotactic biopsy procedures. Meanwhile, FDA was obtaining regular surveillance reports on adverse medical events associated with x-ray guided interventional breast procedures through



its MedWatch Program and its Medical Device Reporting System. Reported problems included adverse reactions during and after the procedures, equipment problems, and complaints about personnel. During this time, FDA also encouraged professional societies to develop their own programs to address quality assurance issues relating to stereotactic biopsy.

In April 1996, NMQAAC members advised FDA that medical practice had developed to the point where regulation of stereotactic mammography was needed. Further, in May 1996, the ACR unveiled its voluntary program for accrediting stereotactic units as well as personnel performing this procedure.

In October 1996, NMQAAC and FDA met again to discuss these issues. Before the meeting, FDA had extensive discussions with the ACS and ACR on their views and concerns about quality standards. During the meeting, representatives from both medical specialties, as well as patients, reiterated that quality performance was of utmost importance. The debate centered around the necessary baseline qualifications that should be codified by federal regulation. Both the ACS and ACR expressed continuing commitment to open dialogue and exchange of information to build a

consensus regarding standards for personnel and equipment.

FDA's Approach to Interventional Mammography

FDA's goal in regulating mammography is to improve the national baseline performance of this procedure. By discussing the issues before developing and publishing proposed regulations, and soliciting public comment before publishing final regulations, we hope to issue effective and reasonable standards.

To this end, FDA has encouraged professional societies to sponsor and conduct research on quality standards and quality assurance procedures for interventional mammography. FDA also continues to encourage professional societies to develop their own guidelines for practitioners.

The bottom line is that women are entitled to receive high-quality services for the detection and diagnosis of breast cancer.

*Florence Houn, M.D., M.P.H.,
Director, Division of Mammography
Quality and Radiation Programs*

Infection Control for Mammography Equipment

The potential for the spread of infection between mammography patients as a result of repeated use of mammography equipment is of concern to FDA and the MQSA program, although no cases have been documented in the medical literature. As detailed below, FDA currently expects manufacturers to provide purchasers of x-ray and mammography equipment with adequate cleaning and disinfection instructions and is working closely with the manufacturers to address this issue.

In April 1996, the Office of Device Evaluation (ODE) of FDA's Center for Devices and Radiological Health issued a labeling guidance document titled, *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities*. The document recommends that manufacturers provide specific instructions on their labels about how to appropriately clean and disinfect their devices between each use. It also says that cleaning and disinfection are especially important if the patient contact surfaces are contaminated with visible blood or other body fluids.

Cleaning and disinfection methods vary, depending on the design of the equipment, the material used to manufacture the patient contact surfaces, and the type and amount of contamination. Barrier devices, such

as disposable covers that reduce the amount of contamination and possible transmission of microorganisms, may be an acceptable alternative or adjunct to disinfection.

FDA...expects manufacturers to provide...adequate cleaning and disinfection instructions...

For purposes of clarification, some of the terms used in infection control are defined in the literature as follows:

"Cleaning" is the physical removal of adherent visible soil (for example, foreign materials such as proteins, organic residues, blood, serum, or other debris) from an object. The term is used to describe physical action combined with water, detergents, enzymatic products, surfactants, etc., or any combination of these used to remove the foreign

material from a medical instrument or surface.

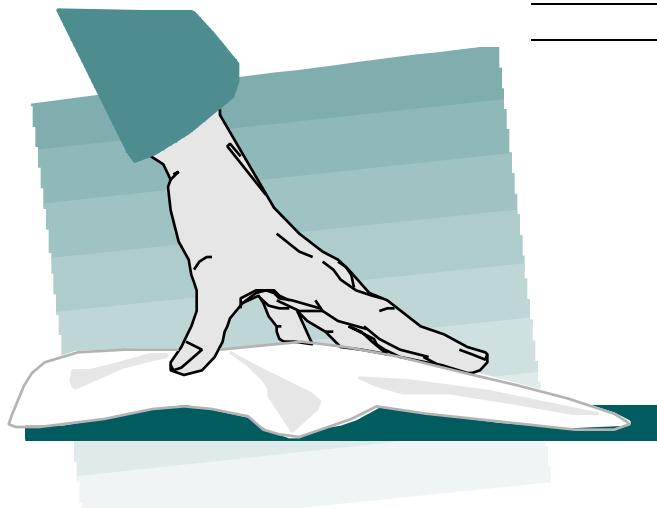
"Low-level disinfection" is the process of killing some viruses and bacteria with a chemical germicide registered as a hospital disinfectant by the Environmental Protection Agency (EPA).

"Intermediate-level disinfection" is the process of killing *M. tuberculosis*, most viruses, and bacteria with a chemical germicide registered as a tuberculocidal agent by EPA.

The policy on disinfection/sterilization practices and the use of barrier devices as preventive measures is based on well-established infection control procedures, as outlined in the Centers for Disease Control and Prevention's (CDC) guidance document on infection control practices (*CDC Guideline for Handwashing and Hospital Environmental Control [1985]*). Two other useful documents are:

- *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers* (AAMI TIR No. 12-1994), and

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Defining “Direct Supervision”

During mammography facility inspections, MQSA inspectors sometimes find that interpreting physicians, radiologic technologists, and/or medical physicists do not meet one or more personnel qualifications. To give these individuals an opportunity to become qualified, FDA has established a policy that allows them to continue to provide mammography services to their facility, provided they do so **only under the direct supervision** of a fully qualified individual.

This approach provides reasonable assurance and safeguards for patients that their mammography procedure will be performed properly. The direct supervision must continue until the individual meets the appropriate qualifications, at which time that individual may resume working independently.

Any physician, physicist, or technologist in training also may gain experience under direct supervision. The definition of direct supervision differs depending upon the type of trainee.

Interpreting Physicians

Direct supervision of an **interpreting physician** during interpretation of mammograms means that the supervising physician reviews, discusses, and confirms or corrects the diagnosis of the physician-in-training. Even though a supervising physician does not have to be present during the physician-in-training's initial interpretation, he or she must review and confirm or correct the diagnosis. Furthermore, before the patient is

informed of the diagnosis, the supervising physician must be identified on the patient's medical record and mammography report.

The interim MQSA regulations require that physicians-in-training read mammograms from at least 240 examinations during a 6-month period. However, even physicians who have read the 240 mammograms cannot read independently unless they have also met the other three initial requirements (being licensed, receiving board certification or 2 months of full-time training in mammography, and completing 40 continuing medical education units in mammography). Physicians working to meet one or more of these qualifications are still considered to be in training and therefore must continue to read under direct supervision.

Radiologic Technologists

Direct supervision of a **radiologic technologist** means that the supervisor must be present to observe and correct, as needed, the performance of the technologist-in-training. The supervisor must, at a minimum, be in the examination room immediately prior to and during the production of mammograms.

Use of Staff Who Don't Meet MQSA Standards

Many facilities, on being informed by their inspector that they have a person on staff who does not meet the MQSA requirements, appropriately have elected to immediately stop using that individual's services. However, some facilities have continued to use such personnel for some period of time after the noncompliant finding has been identified. The latter group of mammography facilities may fail to realize the potential risk to their patients and the increased liability to their facility that may result from a decision to use staff who don't meet MQSA standards.

*Interpreting physicians, radiologic technologists, and medical physicists who do not meet MQSA personnel qualifications may continue to provide mammography services **only under the direct supervision of a fully qualified individual.***

This requirement applies to examinations performed after October 1, 1994, by technologists who have not satisfied the initial qualifications of being state-licensed or having an American Registry of Radiologic Technologists (ARRT) general certificate plus training in mammography.

Medical Physicists

Direct supervision of a **medical physicist** during the survey of the facility's equipment and quality assurance (QA) program means that the supervising physicist must be present to observe and correct, as needed, the performance of the physicist-in-training. The supervisor must be present in the examination room during the majority of the time the survey is being conducted.

This requirement applies to any surveys conducted by a physicist-in-training after October 1, 1994. A

physicist-in-training is one who is still meeting the initial qualification requirement via one of the four options available under MQSA.

MQSA regulations require that experience in surveys be documented for physicists who choose the degree, training, and experience option. This option, however, can only be used until October 27, 1997. The groups

responsible for the other options (board certification and state licensure or approval) may also require survey experience.

The degree, training, and experience option requires that the physicist have 2 years of experience in conducting mammography surveys. As guidance, FDA has said that surveys of 20 units can be considered equivalent to 2 years of experience; the inspector must evaluate physicists who have conducted fewer surveys on a case-by-case basis. Physicists who have met the experience requirement, but not the degree and training requirement, would still be considered physicists-in-training and would have to perform their surveys under direct supervision until they have met all the requirements of this option.

Survey Alert!

We Need Your Help to Improve Our Inspections

Within a few months, you may be one of a small number of randomly selected facilities to receive a survey questionnaire about MQSA inspections. Our goals are to improve inspections and ensure the quality of mammography women receive, while limiting the burdens imposed on facilities.

The responses will help FDA better understand the extent and nature of facilities' perceptions of the positive and negative aspects of the inspection process. A high response rate will provide FDA with the best quality data. Therefore, if you receive a questionnaire, we would appreciate your taking a few minutes to complete and return it within two weeks.

FDA contracted with Booz•Allen & Hamilton, Inc. to conduct the survey to assure that the responses remain confidential and not identifiable with a specific facility.

Meeting the Continuing Education Requirement after October 1, 1997

The Summer 1996 issue of *Mammography Matters* included an article about the end of the 3-year “grace period” for the continuing education requirement for facility staff who met their initial MQSA requirements by October 1, 1994. That article raised a question about how FDA will determine compliance with the continuing education requirement after October 1, 1997.

Because most interpreting physicians, radiologic technologists, and medical physicists who currently provide services to mammography facilities met their initial requirements by the October 1994 date, this question is of direct concern to most staff members.

In addressing this issue, FDA has decided to take the same approach to the continuing education requirement as that announced in the Fall 1996 issue of *Mammography Matters* for the physician's continuing experience requirement. Thus, for the continuing education requirement, a floating rather than a fixed 36-month averaging period will be used. Specifically, at the time of the inspection, a facility will be able to choose as the averaging period either (1) the 36 months immediately preceding the date of the inspection, or (2) the 36 months immediately preceding the last day of the last full calendar quarter before the inspection date.

The inspector will then use the option chosen by the facility to evaluate all of the facility's staff members.



Those who have earned at least 15 continuing education units (CEUs) during the selected 36 months (5 per year x 3 years) will be in compliance with the continuing education requirement. Staff members who fall short of the 15 units must correct this deficiency unless they have not had a full 36-month period since completing their initial requirements.

Those who have not had a full 36-month period since they completed their initial requirements will still be within their “grace period.” No citation will be issued to such personnel, but the facility will be reminded of the need for these individuals to meet the continuing education requirement by the end of their grace period.

FDA has decided to take the same approach to the continuing education requirement as that announced in the Fall 1996 issue of *Mammography Matters* for the physician's continuing experience requirement. Thus, for the continuing education requirement, a floating rather than a fixed 36-month averaging period will be used.

Giving Patients Their Films Upon Request

The interim MQSA regulations state that a facility must comply with a patient's request to transfer records permanently to another facility, a medical institution, a physician, or herself. For temporary transfers of films for comparison studies, FDA suggests that facilities send originals because copies are not always of high enough quality to use as a basis for surgical decisions.

Under the interim regulations, each facility must maintain mammograms and associated files or documentation in a medical record of each patient for (1) a period of not less than 5 years, or

not less than 10 years if no additional mammograms of the patient are performed at the facility, or longer if mandated by state or local law; or (2) until the patient requests that the records be permanently transferred to a medical institution, the physician of the patient, or herself. Thus, the interim regulations only address permanent record transfer, not temporary transfer for comparison studies.

Facilities, by law, must send original mammograms to other physicians or facilities, provided the patient requests that her films be transferred permanently. If a

facility will not send the originals for comparison purposes, FDA suggests that the patient request a permanent transfer. Upon completion of the comparison study (and perhaps any surgery that follows), the patient may request to have the films permanently transferred back to the original facility.

Facilities may ask patients who request a permanent transfer to sign a release form. Facilities that retain a signed release form on record will not be held responsible for maintenance of that patient's films or records during the MQSA inspection.

General MQSA Information

Direct your questions about certification and inspection to:

Mammography Quality Assurance Program
Phone 800-838-7715
Fax 410-290-6351

Documents and other MQSA information are available on the Internet at:

<http://www.fda.gov/cdrh/dmgrp.html>

Submit Requests for MQSA Information to:

MQSA
c/o SciComm, Inc.
PO Box 30224
Bethesda, MD 20824-9998
Fax 301-986-8015

Infection Control

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- *The Association for Professionals in Infection Control and Epidemiology (APIC) Guidelines for the Selection and Use of Disinfectants.*

ODE's current guidance for mammography device manufacturers recommends that devices be visibly labeled as follows: "Patient contact surfaces should be cleaned and disinfected between patients." The guidance also recommends that manufacturers provide appropriate cleaning and disinfection instructions for patient contact surfaces. Another recommendation is that patient contact surfaces be designed to facilitate cleaning and disinfection processes.

Education also plays an important role in disseminating information on infection control practices for mammography practitioners. All mammography facilities and personnel should be aware of and follow the cleaning and disinfection procedures recommended by each manufacturer for its own device(s).

Medical Physicist Meet the MQSA Challenge

Continued from page 1

Response to this expanded role varies considerably, Carolyn notes, depending on the prior experience of the individual medical physicist as well as region- or institution-specific protocols. She points out that overall initial reactions to, and questions about, the regulations are being translated into increased interaction, networking, and information exchange among physicists.

As the MQSA program evolves, physicists and facilities may need to find new ways to work together and plan in advance for on-site visits and equipment checks. Advance planning is essential to testing new equipment before use on patients and is critical to mobile units, which are held to the same standards as fixed units.

Medical physicists can increase their involvement with facilities in a variety of ways, says Marlene McKetty, Ph.D., Medical Radiation Physicist at Howard University College of Medicine. For example, some conduct periodic on-site consultations, hold educational workshops or seminars, or coordinate on-site technologist training courses by manufacturers. Others choose to simply contact facility staff periodically via telephone, electronic mail, or fax.

On-site availability should be built into the arrangement between the medical physicist and facility staff. "Not all problems can be solved

over the phone," Marlene points out. "Sometimes physicists need to review films or see how specific techniques are being carried out. Face-to-face meetings also encourage and strengthen the relationship between the facility and the physicist," she adds.

Beyond the Annual Survey

Facilities hesitant about contacting medical physicists may not fully appreciate the importance of the physicist in resolving technical problems outside the annual survey. Bob gives the example of a facility that had been following voluntary American College of Radiology (ACR) guidelines, but was having trouble producing acceptable phantom image scores on a daily basis as their MQSA inspection drew near. Despite working closely with the film and equipment manufacturers, the facility still was not able to achieve a desirable outcome.

Enter the medical physicist: Bob was called in and suggested various ways to approach and fine-tune what he calls "the elements of the imaging chain," from the screen-film combination to specific quality control (QC) methodology. After implementing specific changes, the facility saw a significant improvement in its phantom image scores and now is operating well within MQSA parameters. And the improved phantom images should lead to improved clinical images.

With an approach that encourages regular dialogue between medical physicists and facility staff, Bob says, facilities see the benefits of

developing a relationship with the medical physicist and including him or her in the mammography team. Marlene agrees, noting that too often in the past early-stage equipment-related problems that could have been resolved were left unaddressed, potentially compromising mammography quality and leading to extensive and costly corrective measures. MQSA and associated regulations attempt to overcome these problems by encouraging the medical physicist to become more involved in a facility's day-to-day operations.

Benefits to Medical Physicists

For Bob, implementing the new regulations has proven to be a "highly satisfying experience, both professionally and personally," in part because of his expanded role in working more directly and more frequently with mammography facilities and staff. He sees MQSA as a way of encouraging medical physicists "to keep a focus on patients and problem solving and to avoid getting buried in numbers and technology."

Those interviewed for this article acknowledge that the style of practice for medical physicists promoted by MQSA requires a transition for both facilities and physicists. Ultimately, this new role can only improve the overall quality of mammography services being provided to women. In brief, Bob says, by outlining ways to improve patient care and quality, MQSA "mandates the right thing to do."

This column provides facility personnel with helpful hints on various technical and equipment issues involved in meeting MQSA requirements.

The Crossover Procedure

FDA has received a number of questions regarding the procedure used when changing from one film emulsion batch to another. These questions indicate that there is some confusion about the procedure. The American College of Radiology (ACR) recently issued a clarification on how the crossover procedure should be conducted.

Definition

The term “crossover” is used to describe the reestablishment of quality control (QC) levels when a transition is made from an existing film emulsion batch to a new film emulsion batch.

(See ACR *Quality Control Manual*, 1994 edition.)



Orhan H. Suleiman, Ph.D., Chief, Radiation Programs Branch, Division of Mammography Quality and Radiation Programs

Action Limits

If the existing operating level for mid-density is 1.25, with an action limit of plus or minus 0.10, then the film is within control over the range of 1.15 to 1.35 optical density. If the film optical density of the new emulsion batch yields a 1.30 mid-density value when the existing control film yields the 1.25 value, then the operating level for mid-density on the QC chart must be **readjusted** by a factor of 0.05. In this case, the new mid-density control level would be 1.30, with action limits of plus or minus 0.10, resulting in new control limits ranging from 1.20 to 1.40.

New QC Levels Needed when Changing Film Emulsion Batch

Differences between emulsion batches result primarily from manufacturing differences and are considered acceptable. However, if new QC levels are not reestablished after a film emulsion batch change, then a facility may incorrectly assume that the deviations from previously determined QC levels are caused by the processor when, in fact, the cause was simply the change in the film emulsion batch.

For Additional Information . . .

For additional information on the crossover procedure, please contact the ACR, 1891 Preston White Drive, Reston, VA 20191, 800-227-6440.

Q & A

Q & A is a regular column in Mammography Matters. We welcome your questions and will publish answers to any that are of general interest. Send your questions to Mammography Matters, FDA/CDRH (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850, Fax 301-594-3306.

Q How much radiation does a woman receive during a routine mammogram? How soon can she have another mammogram?

A For the most common procedures, which make use of a film-fluorescent screen combination as the imaging device, the average glandular dose for the average woman is about 1.5 milligray (or 150 millrad) per exposure.

There is no minimum time limit between mammograms. If the patient's symptoms warrant an additional procedure, the risk from the repeated exposure is very small compared to the potential risk from not obtaining an accurate diagnosis. Women should not delay having a recommended mammogram because of concern about radiation dose.

Q We are a newly accredited facility and would like to know when we will receive our FDA certificate.

A Your facility should receive its FDA certificate within 7 to 10 days after accreditation by your accreditation body. In the meantime, you can expect an Interim Notice within 2 to 3 business days. If you don't receive the Interim Notice after 3 business days, submit a written request via fax to the Mammography Quality Assurance Program at 410-290-6351.

Q Why did I receive a certificate with the same expiration date that the previous one held, when the fact sheet states that the certificate is good for 3 years?

A The new certificate may have been generated to reflect changes in your facility's name and/or address that are activated by your accreditation body. The certification period remains the same. You should return the old certificate to FDA at:

FDA MQSA Program
PO Box 6057
Columbia, MD 21045-6057

Q If a radiological technologist decides to meet the initial mammography training requirement by obtaining 40 hours of training, what types of training are acceptable?

A The 40 hours of training must be formal, organized instruction in appropriate topics by qualified instructors. In general, topics such as positioning or quality control techniques that could lead to improved quality mammography would be considered appropriate. (See *Mammography Matters*, Fall 1996, page 4, for additional information.)

Q What will happen to our facility during the annual inspection if the only physicist's survey performed within the last 14 months is the one already reviewed during the previous annual inspection?

A The inspector will record that the survey has been done, the date of the survey, and other information from the previous physicist's survey report. The inspector will also include on the inspection report a statement saying, "The latest available physicist's survey report was reviewed during the previous annual inspection. It is less than 14 months old and therefore does not constitute a noncompliance."

Q & A (continued)

Q Would you please elaborate on the answer in the last issue of *Mammography Matters* to the question, "What kind of strips work on darkroom doors?"

A Certainly. The answer in the last issue concluded with, "Ultimately, if the darkroom passes the fog test, then any type of strip is adequate."

Unfortunately, some mammography darkrooms with fairly obvious light leaks around the door have passed the fog test. Light leaks can be highly directional and may not affect the fog test but have the potential to fog a film at nearby locations. All visible light leaks should be corrected, even when a darkroom passes the fog test.

Q I'm a technologist who currently has a certificate in radiography and mammography from an FDA-recognized certifying body but have chosen to take some time off from work. I was told FDA is trying to make it mandatory for technologists to perform a certain number of mammograms per year to remain certified. Is this true? If so, what will happen to technologists such as myself?

A It is important for technologists who provide services to mammography facilities to keep their skills sharp through regular performance of their duties. Certainly there would be reason for concern about the quality of examinations performed and the possible health hazards if a technologist returned from an extended absence and immediately resumed performing mammography independently.

With this in mind, FDA included in its proposed final regulations continuing experience requirements for technologists and physicists that correspond to those already existing for physicians. The continuing experience requirements currently are not in effect because they are not part of the present regulations. If they are included in the final regulations, at least a year will be allowed after the publication date before they become effective. Therefore, facilities and staff members will have time to adjust to any new personnel requirements after they are published.

If you decide to take time off from work after the new regulations become effective and, as a result, fail to meet the new requirements, you will be able to go through a requalification procedure.

FDA neither endorses nor requires the use of any specific x-ray system component, measuring device, software package, or other commercial product as a condition for accreditation or certification under MQSA.

Any representations, either orally or in sales literature, or in any other form, that purchase of a particular product is required in order to be accredited or certified under MQSA should be reported to FDA immediately so that appropriate action may be taken.

The mention or illustration of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by FDA.

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If your **mailing label code** includes either:

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Otherwise submit your address changes to:

MQSA, c/o SciComm Inc., PO Box 30224, Bethesda, MD 20824-9998.
Fax 301-986-8015.

Please send your comments
about or suggestions for
Mammography Matters to:

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Articles may be reproduced or adapted for other publications. Comments should be addressed to:

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